REMARKS/ARGUMENTS

Claim 1 has been amended. Claims 25 and 26 have need added. Therefore, claims 1-26 are pending in the application. Applicants submit that the amendments contain no new matter. Reconsideration of the claims in view of the following Remarks is respectfully requested.

35 U.S.C. § 102

Claims 1-4, 6-7, 10-17, 19-20, and 24 stand rejected under 35 U.S.C. 135 102(e) as being anticipated by Bunce et al. Applicants respectfully traverse this rejection.

Independent claim 1 recites an asymmetric porous membrane comprising a blood supply portion, a development portion, and a blood-cell blocking portion formed between the supply portion and the development portion, such that "the blood moves in a direction substantially parallel to a surface of the asymmetric porous membrane by capillary action, and when the blood reaches the blood-cell blocking portion, the movement of blood cells in a direction substantially parallel to the surface is blocked, such that only blood plasma or blood serum moves into the development portion."

Applicants submit that Bunce et al. do not disclose a membrane comprising a blood supply portion, a development portion, and a blood-cell blocking portion formed between the supply portion and the development portion, such that when the blood reaches the blood-cell blocking portion, the movement of blood cells in a direction substantially parallel to the surface is blocked. Rather, Bunce et al. disclose a lateral flow filter device consisting of large pore material 1 in close contact with smaller pore material 2 (column 5, lines 39-41). When whole blood is applied to inlet region 3, plasma quickly flows into small pore material 2, while region 6 of large pore material 1 begins to clog with erythrocytes (lines 60-64). The whole blood, however, continues to move in a direction that is substantially parallel to the surface of the membrane (lines 60-66). Applicants submit, therefore, that the device of Bunce et al. does not comprise a blood-cell blocking portion that prevents the movement of blood cells in a direction substantially parallel to the surface as recited in the present claims.

Applicants submit that the configuration of the invention as recited in the claims separates blood cells in a manner that is completely different from that in the asymmetric porous membrane disclosed by Bunce et al. In the membrane of Bunce et al., blood is gradually

separated into blood cells and blood plasma as it moves inside the membrane. Thus, according to a visual observation of the porous membrane after supplying the blood, gradation in color is seen in the porous membrane. Specifically, in the porous membrane, the red color of the blood will necessarily become paler and paler from upstream to downstream with respect to the flow of the blood and eventually will turn to the transparent color of blood plasma. Therefore, it is difficult to determine at which portion of the membrane the blood cells and the blood plasma are completely separated. Moreover, it cannot be known at which portion of the membrane the blood cells and the blood plasma will be separated before the separation actually occurs. Even if asymmetric porous membranes with the same size are used, the portion at which the blood cells and the blood plasma are completely separated differ from one membrane to another due to differing hematocrit values of blood samples supplied to the membranes.

The structure of the asymmetric membrane as recited in the present claims, by contrast, overcomes these deficiencies. When blood cells that have not been separated reach the blood-cell blocking portion, "only blood plasma or blood serum moves into the development portion." A visual inspection of the present invention, therefore, will clearly indicate that the blood supply portion is red and the development portion is transparent. Therefore, it is very easy to determine at which portion of the membrane the blood cells are completely separated. Furthermore, blood plasma can be collected regardless of the hematocrit value of the sample supplied to the membrane, because the blood-cell blocking portion defines the boundary.

Applicants submit, therefore, that the configuration of the Bunce et al. membrane is completely different from that of the present invention as recited in the claims. Bunce et al. simply does not disclose or suggest the blood-cell blocking portion as recited in the claims. Applicants submit that claims 1-4, 6-7, 10-17, 19-20, and 24 are patentable over Bunce et al. at least for this reason. Withdrawal of the rejection is therefore respectfully requested.

Claims 1, 3, 6-11, 14-21, and 24 stand rejected under 35 U.S.C. 102(b) as being anticipated by Douglas et al. Applicants respectfully traverse this rejection. Independent claim 1 recites an asymmetric porous membrane comprising a blood supply portion, a development portion, and a blood-cell blocking portion formed between the supply portion and the development portion, such that "the blood moves in a direction substantially parallel to a surface of the asymmetric porous membrane by capillary action, and when the blood reaches the blood-cell blocking portion, the movement of blood cells in a direction substantially parallel to the

surface is blocked, such that only blood plasma or blood serum moves into the development portion."

Applicants submit that Douglas et al. do not teach a blood cell blocking portion such that when the blood reaches the blood-cell blocking portion, the movement of blood cells in a direction substantially parallel to the surface is blocked. Rather, Douglas et al. disclose a blood cell blocking portion located on the surface of a membrane that serves to block blood cells from moving in a direction that is perpendicular to the surface (column 15, lines 35-48). Applicants respectfully submit, therefore, that claims 1, 3, 6-11, 14-21, and 24 are patentable over Douglas et al. at least for this reason.

Furthermore, independent claim 1 recites that when blood is supplied to the blood supply portion at a side having larger pores, the blood moves in a direction substantially parallel to a surface of the asymmetric porous membrane by capillary action. The device taught by Douglas et al., however, comprises a microporous membrane formed with a skin side which acts as a red blood cell barrier and a matrix side which has uniform pore size for containing indicator reagents (column 9, lines 27-33). The whole blood is applied to the skin side, and the combination of skin characteristics, hydrophilic matrix, and separation agents hold the red blood cells on the *surface* of the skin side while clear fluid and analytes flow into the matrix (lines 55-58). It is critical that the whole blood is delivered from the skin side to achieve proper separation (lines 59-60).

Thus, in contrast to the present invention as recited in the claims, Douglas et al. teach a blood supply portion having *smaller* pores which block the red blood cells at the skin *surface*. The present invention, by contrast, comprises a blood supply portion having larger pores, and a blood-cell blocking portion "formed between the blood supply portion and the development portion". Applicants submit, therefore, that claims 1, 3, 6-11, 14-21, and 24 are patentable over Douglas et al. at least for this additional reason.

35 U.S.C. § 103

Claims 5, 18, and 21-23 stand rejected under 35 U.S.C. § 103 as being unpatentable over Bunce et al. These claims are allowable at least for the reasons given above for claim 1. Applicants do not concede the relevance of Bunce to the features of claims 5, 18, and 21-23.

Claims 8-9 stand rejected under 35 U.S.C. § 103 as being unpatentable over Bunce et al. in view of Douglas et al. Applicants respectfully traverse this rejection. Similarly to the

previous rejections, Applicants do not concede the relevance of Bunce to the features of these claims, since Bunce does not disclose a membrane comprising a blood supply portion, a development portion, and a blood-cell blocking portion formed between the supply portion and the development portion, such that when the blood reaches the blood-cell blocking portion, the movement of blood cells in a direction substantially parallel to the surface is blocked. Applicants respectfully submit that Douglas et al. does not cure these deficiencies. Therefore, Applicants submit that neither Douglas et al. nor the combination of Douglas et al. and Bunce et al. discloses or suggests a blood testing tool having all limitations of these claims. Withdrawal of this rejection is respectfully requested. Applicants do not concede the relevance of the references to these claims.

Claims 2 and 12-13 stand rejected under 35 U.S.C. § 103 as being unpatentable over Douglas et al. in view of Bunce et al. Applicants respectfully traverse this rejection. As stated above regarding the previous rejections, neither Bunce nor Douglas et al. disclose or suggest an asymmetric porous membrane having a blood-cell blocking portion as recited in the claims. Withdrawal of this rejection is respectfully requested. Applicants do not concede the relevance of the references to these claims.

Finally, claims 4-5 and 22-23 stand rejected under 35 U.S.C. § 103 as being unpatentable over Douglas et al. Applicants respectfully traverse this rejection on the grounds that Douglas et al. does not disclose or suggest an asymmetric porous membrane having a blood-cell blocking portion as recited in the claims. Withdrawal of this rejection is respectfully requested. Applicants do not concede the relevance of the references to these claims.

Summary

Applicants submit that the claims are in condition for allowance and notification to that effect is earnestly solicited. The Examiner is invited to contact Applicants' representative if prosecution may be assisted thereby.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(612) 332.5300

Date: October 14, 2003

Douglas P. Mueller
Reg. No. 30,300